REMARKS

The Office Action dated March 26, 2002, has been received and reviewed. Claims 7-10 and 12-14 are pending in this application. Claims 8, 10 and 12-13 have been amended. Claim 9 has been cancelled without prejudice or disclaimer. Claims 15-18 have been added. The marked up version of the claim amendments is appended hereto and is captioned "Version with Markings to Show Changes Made." The amendments to the specification and specific rejections are addressed below. Applicants respectfully request reconsideration of the application as amended herein and in light of the arguments below.

I. Claim Amendments

Claims 8, 10 and 12-13 have been amended to include the specific sequences of figure 5 and to better clarify the present invention. Claims 15-18 have been added to further clarify the invention and to reduce the confusion created by the multiple dependent claims found in original claims 12-14. Support for claim 18 can be found throughout the application, particularly in view of the discussion regarding FIG 1A-1C. It is respectfully submitted that those of ordinary skill in the art were aware at the time of filing this application that an entire amino acid sequence was not necessarily required for a biological activity and that a fragment of a defined amino acid sequence could be readily tested to determine whether or not it retained androgen receptor activity. Claim 9 has been cancelled without prejudice or disclaimer. Accordingly, Applicants respectfully request reconsideration of the application.

II. Claim Objections

Claims 8-10 stand objected to as allegedly not complying with 37 C.F.R. § 1.821 (d) which requires that a reference to a particular sequence identifier be made in the specification whenever a reference is made to that sequence. Applicants have amended claims 8 and 10 to include the specific sequence identifier. Applicants have cancelled claim 9 thus mooting this rejection. Accordingly, Applicants respectfully request that the claim objections be withdrawn.

III. Claim Rejections 35 U.S.C. § 112, second paragraph

Claims 7 and 12-14 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims stand rejected as allegedly the phrase "DNA sequence encoding human androgen receptor" does not have clear metes and bounds because no structure is provided in the claim limitation. Applicants respectfully disagree with this assessment. Applicants submit that the present application contains two examples of androgen receptor sequences (human and rat). Furthermore, this is the first instance where the androgen receptor has been isolated or in any pure form which would allow for characterization of its structure. Therefore, the present application does point our and distinctly claim the subject matter of the present invention as the present invention discloses a DNA sequence encoding human androgen receptor.

Additionally, Applicants have amended claims 12-13, of which 14 depends from to recite to amended claim 8 which now includes a specific sequence identification number. Therefore, there is a clear mete and bounds in the present set of claims. Accordingly, Applicants submit that the claims are now in condition for allowance and the same is respectfully requested.

IV. Claim Rejections 35 U.S.C. § 112, first paragraph

Claims 7 and 12-14 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that at the time the application was filed, the inventors had possession of the invention. Applicants respectfully disagree with this assessment.

Applicants submit that the present application contains two examples of androgen receptor sequences (human and rat). Comparison of the deduced 919 amino acid sequence of the human androgen receptor to the 902 amino acid sequence of rat androgen receptor reveals identical sequences in the DNA- and hormone-binding domains, with an overall homology of 85%. Therefore, one of skill in the art would be able to isolate and purify a DNA sequence encoding human androgen receptor.

Furthermore, Applicants note that claims 8 and 10 as amended recite sequence identification numbers as those produced by the DNA sequence provided in Figure 5 (human), and the coding region of this sequence. Therefore, it is clear that the Applicants had possession of the invention at the time of filing. In view of these claim amendments, withdrawal of the present rejection is respectfully requested.

Additionally, claims 7-10 and 12-14 also stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that at the time the application was filed, the inventors had possession of the invention. Specifically, the Examiner notes that the sequence in Figure 5 is not the same as the sequence in Figure 5 in parent application 07/182,646. Applicants note that an amendment after allowance to amend Figure 5 was filed and accepted in the parent application to the exact same sequence contained in the present application. Accordingly, Applicants respectfully request that the 35 U.S.C. § 112, first paragraph rejections to these claims be withdrawn.

V. Claim Rejections 35 U.S.C. § 102(e)

Claims 7 and 12-14 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipate by Liao et al., US Patent No. 5,614,620. Applicants respectfully disagree with this rejection.

The Liao patent does disclose and claim a full-length human androgen receptor protein, yet this full-length protein was not disclosed in the Liao et al. application filed on 30 March 1988. US Patent No. 5,614,620 to Liao et al. is based on application SN 08/149,691, which is a continuation of 07/438,775, which is a continuation-in-part of SN 07/312,763; which is a continuation-in-part of 07/253,807 (filed 5 October 1988); which is a continuation-in-part of 07/176,107 (filed 30 March 1988).

The present application was filed on 15 April 1988, two weeks after the initial Liao et al. application (SN 07/176,107) and almost six months before the second of the Liao et al. applications (SN 07/253,807). The first Liao et al. application (the '107 application) provides an incomplete amino acid sequence for the human androgenic receptor. The '107 application was filed before sequence listings were required, and

the sequences are provided only in the Figures. Only Figure 3 provides a DNA or amino acid sequence for the human androgen receptor.

The human androgen receptor sequences provided by Liao et al. in the '107 application (Figure 3) consist of approximately 2700 nucleotides encoding a protein of 733 amino acids. (A copy of the '107 file wrapper was provided in the parent application and will be resubmitted in the present application at the Examiner's request). The issued Liao et al. patent (US Patent No. 5,614,620) claims an isolated and purified DNA sequence of 3715 base pairs encoding a human androgen receptor of 909 amino acids. Applicants note that the first Liao et al. application (SN 07/176,107, filed March 30, 1988), to which the Examiner refers, describes an incomplete amino acid sequence for the human androgen receptor. The '107 application only discloses a truncated human androgen receptor protein of 733 amino acids encoded by a 2708 base pair DNA sequence (Figure 3; file history of '107 application provided with Amendment dated December 29, 1998). The '107 application does not disclose the full-length 909 amino acid sequence that is disclosed in the issued Liao et al. '620 patent (Figure 3). If the Examiner compares the sequences of Figure 3 of the '107 application and Figure 3C of the issued patent, it will be apparent that the final sequence includes an additional 188 amino acids at the amino terminal end of the protein. The androgen receptor amino acid sequence provided in the '107 application is thus only a portion of the final sequence provided in the issued patent.

In addition, the sequence of the human androgen receptor protein disclosed by Liao et al. in the '107 application is incorrect, *i.e.*, the first 27 amino acids shown in Figure 3 of the '107 application are erroneous. The correct sequence begins at amino acid residue 28 (*i.e.*, Thr Ser Ser), which is actually amino acid residue 217 in the correct, full-length human androgen receptor sequence. Thus, the original application filed by Liao et al. discloses a sequence for the human androgen receptor protein that is both incomplete and incorrect.

Again, to reiterate this point, the '107 application describes the generation of an incomplete 2.6 kb cDNA encoding a 2.2 kb open reading frame by restriction digestion and ligation of over-lapping clones (Example 3, pages 11- 12 of the '107 application). In contrast, the issued '620 patent describes how a clone encoding the

full-length human androgen receptor was generated by ligating the originally-described 2.6 kb sequence to an additional 1.6 kb sequence from a third overlapping clone to generate a 3715 base pair sequence encoding a full-length human androgen receptor ('620 patent, Example 3, Col. 9, lines 25-29). This additional work is not described in the '107 application and was added in a continuation-in-part application filed after the filing date of the present application.

For the reasons set forth above, Applicants submit that the sequence of the human androgen receptor protein disclosed by Liao et al., as of the filing date of the present application "has a materially different amino acid sequence" from the presently-claimed full-length human androgen receptor protein. Moreover, the disclosure of the full-length sequence in the '807 continuation-in-part-application (filed October 5, 1988) is not prior art against the present application. Accordingly, Applicants respectfully submit that the presently-claimed sequences are both novel and unobvious over Liao et al., and respectfully request that the rejection on this basis be withdrawn.

Thus, this matter was not disclosed by Liao et al. until continuation-in-part application serial no. 07/253,807 was filed on October 5, 1998. Therefore, the amino acid sequence of the full-length human androgen receptor of Liao et al. is only entitled to a priority date of October 5, 1998, *i.e.*, almost six months after the priority date of the present application. **Accordingly, this teaching in Liao et al. is not prior art against the present application.**

Furthermore, Applicants respectfully point out that even if Liao et al. taught such a material as claimed by the Examiner, neither Liao et al. nor one of ordinary skill in the art would have appreciated that the disclosed sequence was incorrect and, in fact, the correct sequence could be obtained from this putative material. Moreover, the structure of the claimed proteins and compositions would not have been obvious from any such uncharacterized material. Accordingly, Applicants respectfully submit that the claimed proteins and compositions are neither disclosed nor suggested by Liao et al.

In view of the above, Applicants respectfully submit that the Liao et al. patent does not anticipate the present claims. Accordingly, withdrawal of the present rejection is respectfully requested.

CONCLUSION

In view of the amendments and remarks presented herein, applicants respectfully submit that the claims in the instant application define patentable subject matter. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact Applicants' attorney.

Respectfully submitted,

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Susan E. Freedman
Date of Signature: September 25, 2002

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

A marked up version of each of the presently amended claims, high lighting the changes thereto, follows:

8. (Amended) [The] An isolated and purified DNA sequence [according to claim 7,] encoding a human androgen receptor selected from the group consisting of:

a) [said receptor having] the amino acid sequence [set forth in Figure 5] SEQ ID NO: 19;

b) sequences which differ from (a) above due to the degeneracy of the genetic code and which encode a human androgen receptor encoded by (a) above.

Please cancel claim 9 without prejudice or disclaimer.

10. (Amended) [The] An isolated and purified DNA sequence [according to claim 9,] encoding a human androgen receptor selected from the group consisting of:

a) [said DNA sequence having] the nucleotide sequence [as set forth in Figure 5] SEQ ID NO: 18;

b) DNA sequences which differ from the DNA of (a) above due to the degeneracy of the genetic code and which encode a human androgen receptor encoded by (a) above.

12. (Amended) A prokaryotic or eukaryotic host cell transformed or transfected with [a] the DNA sequence [according to any one of claims] of claim 8 [7 to 10].

13. (Amended) A viral or circular DNA plasmid comprising [a] the DNA sequence [according to any one of claims] of claim 8 [7 to 10].

Please add the following claims:

15. (New) A prokaryotic or eukaryotic host cell transformed or transfected with the DNA sequence of claim 10.

16. (New) A viral or circular DNA plasmid comprising the DNA sequence of claim 10.

17. (New) The viral or circular DNA plasmid according to claim 16 further comprising an expression control sequence operatively associated with said DNA sequence.

18. (New) A fragment of the isolated sequence of claim 7, wherein said fragment retains androgen receptor activity.